



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/016,280 | 12/10/2001 | Frank Himmelsbach | 5/1262 | 7351 |

28505 7590 01/07/2005

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,280

Applicant(s)

HIMMELSBACH ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12 and 13 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-9, 12 and 13 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of 10-25-04 has been fully considered. Although the amended claims have overcome the previous rejection of 112 second paragraph, new issues of indefiniteness are noted. Also, an update search yields the following new ground(s) of rejection. Therefore, the finality of the previous action is withdrawn.

Claims 10 and 11 have been cancelled.

Claims 1-9, 12, and 13 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-5, 7-9, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. In claims 1-5, "A" is defined as "imino" which suggests '-N=C-'. However, in all the compound names and structures, the group "amino" or '-NH' is in the position of "A". Therefore, the definition of "A" as "imino" is inconsistent with the compounds made.

Art Unit: 1624

- b. Claim 5 lacks antecedent basis because it recites the limitations of “*N-methyl-N(tetrahydrofuran-3-yl)amino*”, and “*N-methyl-N(tetrahydropyran-4-yl)amino*” in the definition of E, which are not recited in claim 1.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-5, 7-9, 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 6-9 of U.S. Patent No. 6,627,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim quinazolinyl compounds with overlapping substituents. That is, formula (I) of US'634 would render obvious the instant formula (I) when formula (I) of US'634 has the following substituents:

- i. X is nitrogen;

Art Unit: 1624

- ii. R_a and R_b are equivalent to the instant R_a and R_b , which also have the same scope;
- iii. NR_c (and R_c is hydrogen) is equivalent to the instant A;
- iv. CO is equivalent to the instant B (a carbonyl group);
- v. A is equivalent to the instant C with the same scope;
- vi. B is equivalent to the instant D with the same scope;
- vii. C is C_{2-4} -alkyl- NR_4 group, which is equivalent to the instant E as C_{1-4} -alkylamino, or di- $(C_{1-4}$ -alkyl)-amino group.
- viii. R_d is equivalent to the instant R_c as C_{4-7} -cycloalkoxy, or C_{3-7} -cycloalkyl- C_{1-6} alkoxy group.

Formula (I) of US'634 differs from the instant formula by having various rings as a possible terminal group represented by C. However, regarding the overlapping substituents, it would have been obvious to one skilled in the art to select compounds from Formula (I) of US'634 because said compounds would have had the same biological activity and can be incorporated in a pharmaceutical composition to treat many diseases as recited in claims 7-9, 12 and 13.

3. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/023,099 (US 2002/0173509 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because formula (I) of the copending

application renders obvious the instant formula (I), particularly when formula (I) of the copending application has the following substituents:

- ix. R_a is benzyl, 1-phenylethyl, 3-chloro-4-fluorophenyl, and is equivalent to the instant R_b ;
- x. $-NH-CO$ is equivalent to the instant A-B;
- xi. $-CH=CH-$ is equivalent to the instant C;
- xii. $-CH_2-$ is equivalent to the instant D;
- xiii. R_b is equivalent to the instant E when it represents C_{1-4} -alkylamino, or di-
(C_{1-4} -alkyl)amino;
- xiv. R_c is cycloalkyl-alkoxy.

Formula (I) of the copending application differs from the instant formula (I) by having R_b also represents rings such as: morpholino or a group having tetrahydrofuran or tetrahydropyran. Both sets of compounds have the same utility (i.e., treating tumors, diseases of air way, lungs, GI, bile duct, gal baldder, etc.). Therefore, it would have been obvious to select the instant formula (I) from the one claimed in the copending application because one would have expected said formula to have the same biological activity.

Note, the most recent amendment in the copending application 10/023,099 does not have composition and method claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1624


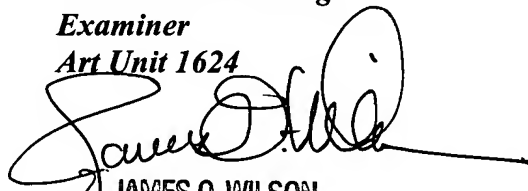
An update search yields the reference of **Himmelsbach et. al.** (WO 00/78735 A1), which appears to teach similar compounds. However, the effective filing date of said reference does not antedate the priority date of this application. Therefore, it is not a competent prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12-02-04


Tamthom N. Truong
Examiner
Art Unit 1624

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600